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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION
OFFICE OF PESTICIDE PROGRAMS
REGISTRATION DIVISION (7505P)

DP BARCODE No.: D387218; FILE SYMBOL No.: 2792-TT; DECISION No.: 444654; PC Code(s): 018301;
Action Code: R 310; FOOD Use: Yes

DATE OUT: July 26, 2011

SUBJECT: End Use Product Chemistry Review
Product Name: DECCO 400 EC

FROM: Shyam Mathur
Product Chemistry Team Leader
Technical Review Branch / Registration Division (7505P)

Shyam Mathur
7-27-11
rm

TO: Rosemary Kearns / Tony Kish, RM 22
Herbicide Branch / Registration Division (7505P)

Company Name: Decco US Post-Harvest, Inc.
Formulation Type: Plant Growth Regulator

INTRODUCTION:

The registrant submitted an application for the registration of the new end use product "DECCO 400 EC." In support of the application, the applicant has submitted 830 series Group A and Group B product chemistry with MRID No. 483721-01, and a basic CSF (dated 01/28/2011). The primary review for the product chemistry data was conducted by Summitec Corporation, Knoxville, TN. TRB has been asked to determine the acceptability of the product chemistry data and the proposed CSF.

SUMMARY OF FINDINGS:

1. Name of Active Ingredient(s): Chlorpropham (38.0%).
2. Has the registrant claimed substantial similarity to a registered product?
[X] Yes; [] No; [] NA; if yes give the registration number of the cited product.
EPA Reg. No: 2792-40
3. All of the source materials of the active ingredient are derived from registered sources- [X] Yes
[] No
4. All inert ingredients have been screened by IIAB and found to be approved for the proposed labeled food uses.

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5. Confidential Statement of Formula(s):

☒ Basic CSF - Dated: January 28, 2011; Resubmitted – Dated:

☐ Alternate CSF(s) - Dated: ; Resubmitted – Dated:

Alternate CSF(s) complies with 40CFR§152.43: ☐ Yes; ☐ No; ☒ NA

6. Product label

a. Ingredient statement: Nominal concentration of AI listed on CSF(s) concurs with product label (PR Notice 91-2).

☐ Yes; ☒ No; if not, explain below:

The nominal concentration of the AI on the product label is not correct and should be 38.0%.

Is the sub statement in compliance with PR Notice 97-6 (inert ingredient vs other ingredient)

☒ Yes; ☐ No; if not, explain below:

Metallic equivalent: ☐ Yes ☐ NA

Soluble arsenic: ☐ Yes ☐ NA

Isomeric ratios: ☐ Yes ☐ NA

Acid equivalent: ☐ Yes ☐ NA; acid equivalent =

b. Health related sub statements: Product contains?

Petroleum distillate at > 10%: ☐ Yes ☒ No ☐ NA

Methanol at > 4%: ☐ Yes ☒ No ☐ NA

Sodium nitrate/Sodium nitrite: ☐ Yes ☒ No ☐ NA

c. Physical chemical hazard statement: Product label requires a statement per 40 CFR §156.78 for: flammability, explosive potential or electric insulator breakdown?

☐ Yes ☒ No

Is the sub statement in compliance with PR Notice 98-6 (Total Release Fogger)?

☐ Yes, ☐ No; ☒ NA; if not, explain below:

d. Label requires an additional Storage and Disposal statement: ☐ Yes ☒ No; if yes explain below:

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7. Group **A**: Product Chemistry Data

TRB's determination of the acceptability of the data for the proposed product is listed in the tables below.

Guideline No.	Study Title		Data submitted		TRB's Assessment of Data	MRID Nos.
			Yes	No		
830.1550	Product Identity & Composition		X		N	CSF (01/28/2011), 483721-01
830.1600	Description of materials used to produce the product		X		N	483721-01
830.1650	Description of formulation process		X		A	483721-01
830.1670	Discussion on the formation of impurities		X		A	483721-01
830.1700	Preliminary analysis		X		NA	CSF (01/28/2011)
830.1750	Certified limits (158.350)	Standard certified limits	X		A	
		Proposed Limits			NA	
		Justification for wider limits			NA	
830.1800	Enforcement analytical method		X		A	483721-01

A = Acceptance, N = Not Acceptable, G = Data Gap,
W = Waiver Request, I = In Progress, NA = Not Applicable, U = Upgradeable.

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8. Group **B**:

Guideline No.	Study Title	Value or Qualitative Description	TRB's Assessment of Data	MRID Nos.
830.6303	Physical State	Liquid	A	483721-01
830.6315	Flammability	The product contains no flammable components.	A	483721-01
830.6316	Explosibility	The product contains no explosive components.	A	483721-01
830.7000	pH	6.7 at 25 °C (1% water suspension)	A	483721-01
830.7300	Density (units)	1.052 g/mL or 8.779 pounds/gal	A	483721-01

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CONCLUSIONS:

TRB has reviewed the CSF and product chemistry data for the proposed end use product and has concluded:

1. The data submitted corresponding to guidelines 830.1550 (product identity and composition) and 830.1750 (certified limits) are not acceptable because of the following reasons:
 - The nominal concentration of the AI on the product label does not match the CSF (Jan 28, 2011). The product label claim nominal concentration is 40% for the AI, whereas, the NC of the AI in the proposed basic CSF is 38%.
 - The nominal concentration of the AI in the CSF has been calculated incorrectly. Based on the purity 99% of the registered source of AI (Reg. No. 2792-67) the NC of the AI in the proposed product will be 37.62%. The registrant must either change the product label or the CSF so that the information on the CSF and on the product label concurs.
 - No chemical name for AI is listed on the CSF. The registrant must provide the chemical name and purity of the source AI used to formulate the proposed product.
 - The information in column #11 of the CSF for the active ingredient must be provided correctly.
 - The Box #8 for pH in the CSF has not been completed. The correct value of pH as provided in group B product chemistry data must be provided in Box #8 of the CSF.
 - The total weight in Box #17 of the CSF has not been provided.

The registrant must provide corrected CSF & the product label for the proposed product.

2. The data submitted corresponding to guideline 830.1600 (description of the materials used to produce the product) are not acceptable. No MSDS sheets for any ingredients were submitted. The registrant must provide the MSDS's for all the starting materials used in the formulation of the proposed product.
3. The data submitted corresponding to guidelines 830.1650 (description of the formulation process), 830.1670 (discussion of the formation of impurities) and 830.1750 (certified limits) are acceptable.
4. No details for the determination of Group B product chemistry data corresponding to guidelines 830.7000 (pH), 830.7100 (viscosity) and 830.7300 (density) were provided. Only the results were included in MRID 483721-01.
5. One-year storage stability (guideline 830.6317) studies are in progress. The results must be submitted upon completion. It is recommended that the observations should be made at 0, 3, 6, 9, and 12 month intervals. No studies for corrosion characteristics (guideline 830.6320) have been planned as the registrant claimed that "the product does not contain any corrosive ingredient."
6. The product name on the product label is "DECCO 400 EC," while the cover letters, data matrix and MRID 483721-01 all refer to the product as "DECCO CIPC 400 EC." The correct name of the product must be provided on the CSF & the product label.

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7. The proposed product (File Symbol No. 2792-TT) was determined not to be substantially similar to the cited product (EPA Reg. No. 2792-40) from the product chemistry point of view. The nominal concentration of AI (38%) in the proposed product is significantly different than the nominal concentration of the AI (25%) in the cited product. Also the flash point (66°F) in the cited product will trigger Physical-chemical hazard warning on the product label, whereas, on the proposed product the flash point is indicated as "NA", consequently the product labels for the two products will not be similar.
8. The proposed label was screened as it pertains to the product chemistry requirements. The final review of the proposed label and uses are the purview of the RM team.

*Similar for
directions for
use only*

DATA EVALUATION RECORD

**CHLORPROPHAM
(DECCO 400 EC)**

STUDY TYPES: Product Identity and Composition (OPPTS 830.1550)
Description of Materials Used to Produce the Product (OPPTS 830.1600)
Description of the Formulation Process (OPPTS 830.1650)
Discussion of Formation of Impurities (OPPTS 830.1670)
Preliminary Analysis (OPPTS 830.1700)
Certified Limits (OPPTS 830.1750)
Enforcement Analytical Method (OPPTS 830.1800)
Physical and Chemical Characteristics (OPPTS 830.6302-830.7950)

MRID 483721-01

Prepared for
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Task Order No. 3-A-59

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Signature: Maolian Chen, Ph.D.
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Date: JUL 16 2011

Disclaimer

This review may have been altered subsequent to the contractor's signatures above.